REMARKS

Applicants respectfully request reconsideration of this application in view of the above amendments and the following remarks.

Claims 1-3, 5-15 and 17 are pending. Claims 1, 6, 8, 10, 12, and 14 are independent and have been further amended herein.

Claims 1-3 and 5-17 have been rejected under 35 U.S.C. §112, first paragraph, as not enabled by the specification. The Examiner argues the specification does not reasonably provide enablement for vanilloid compounds, including capsaicin. The Examiner cites Vazquez-Olivenicia et al. and Yerra et al. to show that vanilloid compounds have different effects on gastric motility, and one skilled in the art would therefore have to perform undue experimentation to determine which vanilloid compounds in what amounts would be effective as laxatives.

Applicants disagree. Applicants maintain the specification provides full enablement for vanilloid compounds, as previously explained. Appropriate amounts of vanilloid compounds are given on page 3, lines 3-4. The first and second full paragraphs of page 3 give further details and examples of vanilloid compounds. Applicants maintain this rejection is without merit.

Claims 1-3 and 5-17 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite. The Examiner argues that the claims omit an effective amount of bisacodyl or enteric coated vanilloid compound. Applicants have amended the independent claims herein to recite " an effective amount of a laxative selected from the group consisting of bisacodyl and enteric coated vanilloid compounds," as suggested by the Examiner.

Claim 14 has also been further amended to recite "administering to a human an effective amount of a laxative selected from the group consisting of bisacodyl and enteric coated vanilloid compounds with about 10 mg to about 500 mg per dose of simethicone."

Claim 16 has been canceled, as its subject matter is contained in claim 14.

Claims 1, 3, 5, 6, 8, 10, 12, and 14-16 have been rejected under Section 103(a) as obvious over Drug Launches (1993) in view of the acknowledged prior art (specification, page 1, lines 27-31, referencing US 5,418,220 disclosing simethicone used in the treatment of constipation), Schmidt et al. (US 5,424,064), Holtman et al. and Sable et al. Drug Launches (1993) is cited to show a composition containing bisacodyl and simethicone. The Examiner

argues that the prior art further suggests it is known that simethicone is suitable for increasing intestinal motility. The Examiner states, "the prior art teaches the combination of bisacodyl and simethicone and that fullness or bloating are gas-related or linked to disturbed gastrointestinal motility (See Holtman et al.). As such, one of ordinary skill in the art would be motivated to combine bisacodyl and simethicone with the expectation that the combination would be more effective in treating fullness or bloating."

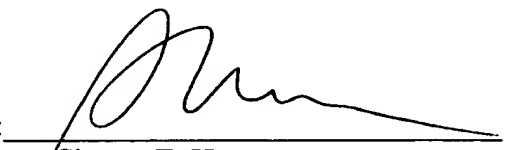
Applicants maintain that this does not suggest the claimed invention. Holtman teaches that fullness or bloating are gas-related or motility-related, and this alternative information does not suggest the claimed invention. Even if, as the Examiner argues, one would expect the combination of bisacodyl and simethicone to be more effective in treating fullness or bloating based on Holtman, this does not translate into an expectation that the combination would increase intestinal motility, since the abstract indicates these as alternative theories.

Applicants again point to their data in Example 1, in which the use of simethicone alone had no effect on small bowel transit in rats treated therewith. Accordingly, the Examiner assertion that simethicone is known to increase intestinal motility appears is speculative and contradicted by applicants' data.

For these reasons, applicants submit that the claims as amended are patentable. Early and favorable reconsideration is requested.

Attached hereto is a marked-up version of the changes made to claims by the current amendment.

Respectfully submitted,

By: 

/Sharon E. Hayner
Reg. No. 33,058

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2242
Dated:

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 4 has been canceled.

Claims 1, 6, 8, 10, 12 and 14 have been amended as follows:

1. (amended) A composition comprising:

a) a laxative selected from the group consisting of bisacodyl and enteric coated vanilloid compounds; and

b) simethicone in an amount ~~effective to enhance the efficacy of the laxative~~ of about 10 mg to about 500 mg per dose.

6. (amended) A method of treating constipation comprising administering to a human an effective amount of a composition comprising:

a) a laxative selected from the group consisting of bisacodyl and enteric coated vanilloid compounds; and

b) simethicone in an amount ~~effective to enhance the efficacy of the laxative~~ of about 10mg to about 500 mg per dose.

8. (amended) A method of improving gastro-intestinal motility in a human comprising administering an effective amount of a composition comprising:

a) a laxative selected from the group consisting of bisacodyl and enteric coated vanilloid compounds; and

b) simethicone in an amount ~~effective to enhance the efficacy of the laxative~~ of about 10 mg to about 500 mg per dose.

10. (amended) A method of treating diabetic gastro-paresis comprising administering to a human an effective amount of a composition comprising:

a) a laxative selected from the group consisting of bisacodyl and enteric coated vanilloid compounds; and

b) simethicone in an amount ~~effective to enhance the efficacy of the laxative~~of about 10 mg to about 500 mg per dose.

12. (amended) A method of treating gastro-esophageal reflux disorder comprising administering to a human an effective amount of a composition comprising:

a) a laxative selected from the group consisting of bisacodyl and enteric coated vanilloid compounds; and

b) simethicone in an amount ~~effective to enhance the efficacy of the laxative~~ of about 10 mg to about 500 mg per dose.

14. (amended) A method for enhancing the efficacy of a laxative selected from the group consisting of bisacodyl and enteric coated vanilloid compounds comprising ~~providing~~ administering to a human therewith ~~an effective amount of~~ about 10 mg to about 500 mg per dose of simethicone.